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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,193	08/12/2005	Peter Gingras	14188-003US1	3946
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EXAMINER SIMPSON, SARAH A				
ART UNIT 3731		PAPER NUMBER		
NOTIFICATION DATE 06/01/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/525,193

Applicant(s)

GINGRAS, PETER

Examiner

SARAH A. SIMPSON

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-12 and 14-30 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14, 19 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement is made of the amendment filed 3/02/2009, amending the drawings, amending claims 1, 3, 4, 6, 7, 14, 25 and 26, canceling claims 5, 13 and 31 and withdrawing claims 15-18 and 20-22. Accordingly, previous objections made to the claims and drawings have been overcome. Also, 35 U.S.C 112 rejections made to claims 3-7 have been overcome. Therefore, claims 1-4, 6-14, 19 and 23-30 are currently pending in the present application and are presented for examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1-4, 6, 8, 10, 12, 14, 19, 25 and 26** are rejected under 35 U.S.C. 102(e) as being anticipated by **Rousseau (US 6,425,924 B1)**.

Regarding claims 1, 10, 19, 25 and 26, Rousseau discloses a sterile three-dimensional biocompatible implant, the implant comprising: a subassembly (10) that resists compression when implanted in a warm-blooded animal, the subassembly

comprising a plurality of elongate elements ((12) wires that make up the mesh) configured to extend through a body opening and make a conical form (fig. 1); and a substantially planar anchor (26) coupled to the plurality of elongate elements, the plurality of elongate elements tapering outwardly in a direction extending away from the anchor, and the plane of the anchor configured to be substantially perpendicular to a longitudinal axis of the body opening when the anchor is located within a body cavity (figs. 1-3). The implant may be made of a biocompatible non-absorbable polymer such as polypropylene (column 5, lines 27-34).

Regarding claim 2, Rousseau discloses the implant of claim 1, wherein the subassembly comprises woven fibers (column 5, lines 27-31).

Regarding claims 3, 4, 6 and 8, Rousseau discloses the implant may be constructed in a variety of ways and may be woven, knitted or non-woven porous textile suitable for reinforcing tissue (column 5, lines 27-31; abstract). The implant may also include an internal support (28).

Regarding claim 12, Rousseau discloses the implant of claim 1, further comprising an onlay (14).

Regarding claim 13, Rousseau discloses the implant of claim 1, further comprising an anchor ((2); figs. 3-4; column 2, lines 15-18).

Regarding claim 14, Rousseau discloses the implant of claim 1, further comprising a means for stabilizing the implant during placement within a warm-blooded animal (figs. 3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 7, 11, 23, 24 and 27-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rousseau (US 6,425,924 B1)**.

Regarding claim 7, Rousseau discloses the invention except for wherein the elongate elements are arranged in a braided pattern.

However, Rousseau teaches the implant may be constructed in a variety of ways and may be woven, knitted or non-woven porous textile suitable for reinforcing tissue (column 5, lines 27-31; abstract).

Given the teachings of Rousseau, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Rousseau with a

braided pattern. The substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Regarding claims 11 and 27-30, Rousseau discloses the invention except for where wherein the implant comprises polyaryletherketone, PGA, PLA, polycaprolactone, polyhydroxylkanoate, or collagen.

However, Rousseau teaches numerous biocompatible synthetic or natural absorbable and nonabsorbable materials can be used for the implant (column 5, lines 27-31).

Given the teachings of Rousseau it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the implant of Rousseau with polyaryletherketone, PGA, PLA, polycaprolactone, polyhydroxylkanoate, or collagen. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claims 23 and 24, Rousseau discloses the implant except for wherein the implant has a surface area to volume ratio less than about 5, 4, 3, 2 or 1.

However, Rousseau teaches from the figures a surface area to volume ratio that appears to be less than about 5, 4, 3, 2 or 1 (figs. 1-4).

Given the teachings of Rousseau, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the implant of Rousseau with a surface area to volume ratio of less than about 5, 4, 3, 2 or 1. Doing so would allow for a greater volume of affected tissue to be held open with minimal contact, reducing

tissue irritation. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-14, 19 and 23-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
5/23/09